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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

September 30, 2003

MEMORANDUM

SUBJECT: **Zinc Phosphide**: Health Effects Division (HED) Human Health Risk Assessment
PP#9E05082 on Potato.
PP#0E06199 on Timothy.
PP#2E06419 on Alfalfa.
PP#1E06270 on Dry Bean.
PP#1E06292 on Wheat.
PP#1E06306 on Barley.
PP#1E06337 on Sugar Beet.

DP Barcodes:	D256974, D285838, D285841, D285844, D285847, D286064, D286630, D286635	*Case Nos.:*	291823, 294054, 293324, 294104, 294888, 294392, 293896, 293253
PC Code:	088601	*Submission:*	S561818, S622276, S622281, S622273, S622271, S622270, S624031, S624033
40 CFR 180.	284	MRID Nos.:	44801701, 45374101, 45186401, 45388401, 45616201, 45460601, 45350701, 44812301

FROM: Bill Wooge, Biologist
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9/30/03

THROUGH: Stephen Dapson, Ph.D., Branch Senior Scientist
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TO: Shaja Brothers/Robert Forrest
PM Team 5
Registration Division (7505C)

The Health Effects Division (HED) of the Office of Pesticide Programs (OPP) is charged with estimating the risk to human health from exposure to pesticides. The Registration Division of OPP has requested that HED evaluate hazard and exposure data and conduct dietary, occupational, residential and aggregate exposure assessments, as needed, to estimate the risk to

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human health that will result from proposed use of zinc phosphide on alfalfa, barley, sugar beets, timothy, potato, dry beans and wheat. Permanent tolerances are now proposed for the crops of alfalfa, barley, sugar beets, timothy, potato, and wheat (which currently are all Section 18 crops) and for the new use of dry beans.

A summary of the findings and an assessment of human risk resulting from the proposed permanent tolerances is provided in this document. The residue chemistry data review has been provided by Nancy Dodd (RAB3), the hazard characterization has been provided by Stanley Gross (RAB3), the occupational and residential assessment has been adopted from the RED, and the environmental fate and drinking water assessment by James K. Wolf of the Environmental Fate and Effects Division (EFED).

Recommendations for Tolerances and Registration

Provided revised Sections B and F with the modifications specified in Section 8.0 of this risk assessment are submitted, the residue chemistry and toxicological databases support the establishment of registrations (except conditional registrations for dry beans and timothy) and permanent tolerances for residues of zinc phosphide in/on the following raw agricultural commodities (RACs):

Commodity	Proposed Tolerance (ppm)
alfalfa, forage	0.2
alfalfa, hay	0.2
barley, grain	0.05
barley, hay	0.2
barley, straw	0.2
bean, dry	0.05
beet, sugar, tops	0.2
beet, sugar, roots	0.05
timothy, hay	0.5
timothy, forage	0.5
potato	0.05
wheat, grain	0.05
wheat, hay	0.05
wheat, straw	0.05
wheat, forage	0.05

HED recommends that conversion of conditional registrations for dry beans and timothy to unconditional registration may be considered upon submission of the following data:

❑ Storage stability data were not provided for dry beans and timothy hay. Storage stability

data for dry beans stored for 96 days and timothy hay stored for 380 days must be submitted as a condition of registration.

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1.0 Executive Summary

Zinc phosphide (Zn_3P_2) is a rodenticide that reacts with the acidic conditions in the gut to form phosphine gas, which interferes with cell respiration. This rodenticide is used to control many species of rodents, including mice, ground squirrels, prairie dogs, voles, moles, rats, muskrats, nutria, and gophers. It is a restricted use pesticide due to hazard to non-target species. Current registrations for Zinc phosphide include both food and nonfood use sites. Existing food uses include grapes, rangeland grasses, and sugarcane. Nonfood uses include indoor or outdoor spot treatment for rodents as well as around burrows or underground in orchards, vineyards, various food crops, rangelands, and non-crop areas. Zinc phosphide is formulated as a bait/solid, dust, granular, pellet/tablet or wettable powder and may be applied by bait box, hand baiting, and broadcast baiting by ground or aerial equipment. Zinc phosphide is proposed for use on alfalfa, barley, dry bean, sugar beet, timothy, potato, and wheat by IR-4 as minor use ("E") petitions with regional registration. Applications will be made post-emergence and broadcast by ground equipment.

Hazard Assessment

Zinc phosphide has high acute toxicity via the oral and inhalation routes (Toxicity Category I) but has low to moderate toxicity via the dermal route (Toxicity Category III). Zinc phosphide is not a skin or eye irritant (Toxicity Category IV). Although a requirement for a skin sensitization study conducted using the technical grade zinc phosphide was waived, a study conducted on guinea pigs using an end-use zinc phosphide product did not produce skin sensitization. Based on the physical properties of the chemical, dermal absorption is expected to be very low, since zinc phosphide reacts with water and stomach acid to produce the toxic gas phosphine from oral, but not dermal exposure. In a developmental toxicity study in rats, the maternal toxicity NOAEL was determined to be 2.0 mg/kg and the LOAEL was 4.0 mg/kg based on mortality. The developmental toxicity NOAEL was at or above 4.0 mg/kg, which was the highest dose tested. The available database does not indicate a potential for increased sensitivity to infants or children, however, it does not include a developmental study in rabbits or a two-generation reproduction study in rats. The requirement for these data were waived in the Reregistration Eligibility Decision (RED Zinc Phosphide, EPA 738-R-98-006, July 1998). The mutagenicity of zinc phosphide is inconclusive: zinc phosphide was negative for gene mutation in the Ames test, positive for gene mutation in a mouse lymphoma assay and negative for mutagenicity in a mouse micronucleus test. The requirement for carcinogenicity studies has been waived for zinc phosphide because chronic exposure is expected to be negligible and long-term testing is unlikely to provide any additional hazard information. Since residues have not been detected in food forms directly eaten by humans, the requirement for a metabolism study with zinc phosphide has been waived.

FQPA Considerations

The Food Quality Protection Act (FQPA) provides that EPA apply an additional tenfold margin of safety for infants and children to account for pre- and post-natal toxicity and the completeness of the toxicity and exposure database, unless EPA determines that a different margin of safety will be safe for infants and children. The HED FQPA Safety Factor Committee (4/19/99) concluded that a 10X FQPA Safety Factor be retained for zinc phosphide and that the factor is applicable to all exposure durations and subpopulations. Because this 10X safety factor was retained for an incomplete database regarding pre- and -postnatal toxicity (rabbit developmental and a 2-generation rat reproduction studies with zinc phosphide are lacking), there is no need for a hazard reevaluation under the new 2002 FQPA 10X policy. The zinc phosphide team has reviewed the database for exposure and has determined that an additional safety factor is not required for exposure. HED has high confidence in the residue chemistry data showing no potential for dietary exposure in foods and in the environmental fate data showing no potential for drinking water exposure.

Dietary Exposure

The Agency has previously concluded that acute or chronic dietary exposure associated with the use of zinc phosphide is unlikely (Zinc Phosphide RED, EPA 738-R-98-006, July 1998). In this present assessment of dietary exposure and risk from the proposed uses of zinc phosphide it was concluded that acute or chronic dietary exposure is also unlikely. Thus, quantitative acute dietary, chronic dietary, and cancer assessments were not conducted for zinc phosphide. Residue data from field trials conducted to support the proposed registrations [alfalfa, barley bean (dry) beet (sugar), potato, timothy and wheat] uphold the previous conclusion that acute or chronic dietary exposure to zinc phosphide in food is unlikely. Residues were below the LOQs (<0.05 or <0.1 ppm) in most of the crops; the exceptions are livestock feeds. These residue data provide considerable evidence that finite residues of zinc phosphide are not present on human food items. Because residues of zinc phosphide ingested by livestock would be immediately converted to phosphine and metabolized to naturally occurring phosphorus compounds, residues of zinc phosphide in livestock feeds are not expected to result in residues of zinc phosphide in livestock commodities. Also, zinc phosphide will not concentrate during the processing of any commodity because the act of processing will not allow for unreacted zinc phosphide to remain in or on processed food items. Notwithstanding the absence of exposure, HED established acute and chronic RfDs for zinc phosphide.

Drinking Water Exposure

No drinking water risk assessment was performed for zinc phosphide because no residues are expected in either ground or surface water.

Residential Exposure

There were no endpoints identified for use in a residential assessment except for accidental ingestion. Although having considered that accidental ingestion of zinc phosphide baits may occur with respect to a very small number of children, EPA has concluded that this potential exposure is not appropriate for inclusion in evaluating the safety of aggregate exposure of consumers and major identifiable subgroups of consumers to zinc phosphide. Unlike other residential uses (such as a turf use) that potentially may result in exposures to significant groups of children, the subgroup of children that may consume baits in childproof bait stations is very tiny. This small subgroup of children would not qualify as a major identifiable subgroup of consumers.

Occupational Assessment

Dermal and inhalation endpoints for zinc phosphide have not been selected and/or established and therefore quantitative occupational assessment has not been conducted. The Agency has, however, identified several occupational scenarios where inhalation of particulates and/or dusts may occur. In order to minimize these occurrences, the Agency adopted labeling requirements for several formulations in the Zinc Phosphide Reregistration Eligibility Decision (EPA 738-R-98-006, July 1998).

Recommendations for Tolerances and Registration

Provided revised Sections B and F with the modifications specified in Section 8.0 of this risk assessment are submitted, the residue chemistry and toxicological databases support the establishment of registrations (except conditional registrations for dry beans and timothy) and permanent tolerances for residues of zinc phosphide in/on the following raw agricultural commodities (RACs):

Commodity	Proposed Tolerance (ppm)
alfalfa, forage	0.2
alfalfa, hay	0.2
barley, grain	0.05
barley, hay	0.2
barley, straw	0.2
bean, dry	0.05
beet, sugar, tops	0.2
beet, sugar, roots	0.05
timothy, hay	0.5
timothy, forage	0.5
potato	0.05
wheat, grain	0.05
wheat, hay	0.05
wheat, straw	0.05
wheat, forage	0.05

HED recommends that conversion of conditional registrations for dry beans and timothy to unconditional registration may be considered upon submission of the following data:

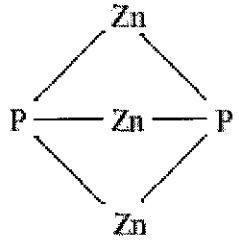
- ❑ Storage stability data were not provided for dry beans and timothy hay. Storage stability data for dry beans stored for 96 days and timothy hay stored for 380 days must be submitted as a condition of registration.

2.0 Zinc Phosphide Physical/Chemical Properties Characterization

2.1 Identification of Active Ingredient

- ❑ Common Name: Zinc Phosphide
- ❑ Chemical Name: Trizinc diphosphide
- ❑ Chemical Family: Inorganic rodenticide
- ❑ CAS Registry Number: 1314-84-7
- ❑ OPP Chemical Code: 088601
- ❑ Empirical Formula: Zn_3P_2

2.2 Structural Formula



2.3 Physical/Chemical Properties

Technical zinc phosphide is a gray to black powder with a phosphine odor and melting point of 420 C. Zinc phosphide is insoluble in water and ethanol, and soluble in benzene and carbon disulfide. Zinc phosphide is stable in dry conditions, but reacts slowly with water (including atmospheric moisture) to form phosphine gas. The following table (Table 1) summarizes the chemical/physical properties for zinc phosphide:

Table 1. Zinc Phosphide Chemical/Physical Properties

Parameter	Value
Molecular weight	258.09
Melting point/range	420°C
Density	4.51 (20°C)
Water solubility	Insoluble in water
Solvent solubility	Soluble in benzene and carbon disulfide. Insoluble in ethanol.
Vapor pressure	Negligible in the dry state (solid)

3.0 Hazard Characterization

The toxicology data were reviewed for the Zinc Phosphide Reregistration Eligibility Decision (EPA 738-R-98-006, July 1998). The existing toxicological database for zinc phosphide supports the establishment of permanent tolerances for residues of zinc phosphide on the crops of alfalfa, barley, sugar beets, timothy, potato, and wheat (which currently are all Section 18 crops) and for the new use of dry beans.

3.1 Hazard Profile

Zinc phosphide has high acute toxicity via the oral and inhalation routes (Toxicity Category I) but has low to moderate toxicity via the dermal route (Toxicity Category III). Zinc phosphide is not a skin or eye irritant (Toxicity Category IV). Although a requirement for a skin sensitization study conducted using the technical grade zinc phosphide was waived, a study conducted on guinea pigs using an end-use zinc phosphide product did not produce signs of skin sensitization. Based on the physical properties of the chemical, dermal absorption is expected to be very low, since zinc phosphide reacts with water and stomach acid to produce the toxic gas phosphine from oral, but not dermal exposure. In a developmental toxicity study in rats, the maternal toxicity NOAEL was determined to be 2.0 mg/kg and the LOAEL was 4.0 mg/kg based on mortality. The developmental toxicity NOAEL was at or above 4.0 mg/kg, which was the highest dose tested. The available data base does not indicate a potential for increased sensitivity to infants or children, however, it does not include a developmental study in rabbits or a two-generation reproduction study in rats. The requirement for these data were waived in the Reregistration Eligibility Decision (RED Zinc Phosphide, EPA 738-R-98-006, July 1998). The mutagenicity of zinc phosphide is inconclusive: zinc phosphide was negative for gene mutation in the Ames test, positive for gene mutation in a mouse lymphoma assay and negative for mutagenicity in a mouse micronucleus test. The requirement for carcinogenicity studies has been waived for zinc phosphide because chronic exposure is expected to be negligible and long-term testing is unlikely to provide any additional hazard information. Since residues have not been detected in food forms directly eaten by humans, the requirement for a metabolism study with zinc phosphide has been waived.

3.1.1 Acute Toxicity

The following table (Table 2) summarizes the acute toxicity profile for zinc phosphide:

Table 2. Acute Toxicity Profile*

GDLN	Study Type	MRID	Results	Toxicity Category
870.1100	Acute Oral	00085366	Gavage LD_{50} for rats 21 (13-35) mg/kg	I
870.1200	Acute Dermal	00006030	LD_{50} Dermal LD_{50} between 2000 and 5000 mg/kg.	III
870.1300	Acute Inhalation	Waived	Acute inhalation: None available	I[1]
870.2400	Primary Eye Irritation	00029247	Eye irritation: Slight conjunctival redness, chemosis and discharge decreasing in severity in 72 hrs.	IV
870.2500	Primary Skin Irritation	00006029	Dermal irritation PID = 0.0, non irritating.	Non-irritant
870.2600	Dermal Sensitization	Waived	Dermal sensitization -- none available.	--

[1]In lieu of performing study, zinc phosphide was designated as Toxicity Category 1

* From HIARC & FQPA SF Committees, 4/19/1999 (HED Doc. 01332).

3.1.2 Toxicity Profile

The following table (Table 3) summarizes the toxicity profile for zinc phosphide:

Table 3. Toxicology Profile

Guideline No.	Study Type	MRID No. (year)/ Classification/ Doses	Results
870.3100	90-Day oral toxicity rodents (rats)	43436601 (1994) Acceptable Gavage 0, 0.1, 1.0, 3.0 mg/kg/day	NOAEL = 0.1 mg/kg/day LOAEL = 1.0 mg/kg/day based on increased mortality and kidney hydronephrosis in male rats
870.3100	90-Day oral toxicity rodents (mouse)	Waived	-
870.3150	90-Day oral toxicity in nonrodents (dogs)	Waived	-
870.3200	21/28-Day dermal Toxicity (rats)	Waived	-
870.3700	Prenatal developmental in rodents (rats)	43083501 (1994) Acceptable 0, 1.0, 2.0, 4.0 mg/kg/day	Maternal NOAEL = 2 mg/kg/day Maternal LOAEL = 4 mg/kg/day based on mortality Developmental NOAEL = >4 mg/kg/day Developmental LOAEL = not established
870.3700	Prenatal developmental in non rodents (rabbit)	Waived	-
870.3800	Reproduction and fertility effects (rats)	Waived	-
870.4100a	Chronic toxicity rodents (rat)	Waived	-
870.4200a	Carcinogenicity Mouse	Waived	-
870.4100b	Chronic toxicity dogs	Waived	-
870.5375	Mutagenicity - Mouse Lymphoma	42987302 Acceptable	Positive for gene mutation, with and without S9 mammalian metabolic mutation
870.5385	Mutagenicity - Chromosomal Aberrations	42987303 Acceptable	Negative for gene mutation
870.5500	Mutagenicity - Ames Salmonella	42987301 Acceptable	Negative for gene mutation, with and without S9 mammalian metabolic mutation
870.6200a	Acute neurotoxicity screening battery (rat)	43284301 (1994) Acceptable 0, 1, 5, 10 mg/kg/day	NOAEL = >10 mg/kg/day LOAEL = not established
870.6200b	Subchronic neurotoxicity screening battery (rat)	43903801/43903802 (1995) Acceptable 0, 0.1, 0.5, 2 mg/kg/day	NOAEL = 0.1 mg/kg/day LOAEL = 2.0 mg/kg/day based on clinical toxicity (not neurotoxicity)

3.2 FQPA Considerations

The Food Quality Protection Act (FQPA) provides that EPA apply an additional tenfold margin of safety for infants and children to account for pre- and post-natal toxicity and the completeness of the toxicity and exposure database, unless EPA determines that a different margin of safety will be safe for infants and children. The HED FQPA Safety Factor Committee (4/19/99) concluded that a 10X FQPA Safety Factor be retained for zinc phosphide and that the factor is applicable to all exposure durations and subpopulations. Because this 10X safety factor was retained for an incomplete database regarding pre- and -postnatal toxicity (rabbit developmental and a 2-generation rat reproduction studies with zinc phosphide are lacking), there is no need for a hazard reevaluation under the new 2002 FQPA 10X policy. In addition, the Agency has previously concluded (Zinc Phosphide RED, EPA 738-R-98-006, July 1998) that there will be no dietary exposure as a result of the registered uses of zinc phosphide. This conclusion can be extended to the proposed food uses. The zinc phosphide team has reviewed the database for exposure and has determined that an additional safety factor is not required for exposure. HED has high confidence in the residue chemistry data showing no potential for dietary exposure in foods and in the environmental fate data showing no potential for drinking water exposure.

The RED stated that the Agency believes that "accidental ingestion" of zinc phosphide baits should not be included in the FQPA determination for tolerance setting.

3.3 Dose Response Assessment

The Agency has previously concluded that acute or chronic dietary exposure associated with the use of zinc phosphide is unlikely (Zinc Phosphide RED, EPA 738-R-98-006, July 1998). Of those commodities currently designated as food uses for zinc phosphide under existing registrations, only three were found to have detectable residues after application (grasses, sugar beets, sugarcane). Since these three crops are not direct human food items, no acute or chronic dietary consumption of zinc phosphide is expected. Also, zinc phosphide will not concentrate during the processing of any commodity because the act of processing will not allow for unreacted zinc phosphide to remain in or on processed food items. Data from residue field trials conducted to support the proposed registrations [alfalfa, barley bean (dry) beet (sugar), potato, timothy and wheat] uphold the previous conclusion that acute or chronic dietary exposure to zinc phosphide in food is unlikely. Residues were below the LOQs (<0.05 or <0.1 ppm) in most of the crops; the exceptions are livestock feeds. Because residues of zinc phosphide ingested by livestock would be immediately converted to phosphine and metabolized to naturally occurring phosphorus compounds, residues of zinc phosphide in livestock feeds are not expected to result in residues of zinc phosphide in livestock commodities.

Notwithstanding the absence of dietary exposure, acute and chronic RfDs have been established for zinc phosphide and an assessment of doses and endpoints for non-dietary exposure risk assessments has been conducted. The results of these analyses are itemized in Table 4.

Table 4. Summary of Toxicological Dose and Endpoints for Zinc Phosphide for Use in

Human Risk Assessment

EXPOSURE SCENARIO	DOSE (mg/kg/day)	ENDPOINT/STUDY	RATIONALE
Acute Dietary (General Population including Infants & Children	2.0	Maternal Toxicity in Dev. -Rat Study (Mortality)	Mortality beginning on Gestation Day 10 (i.e., after 4 doses) thru GD16. This dose is supported by deaths seen after 1-2 days at 10 mg/kg/day in a developmental toxicity study in mice.. Also, mortality occurred at 5 mg/kg/day in a 22-day range-finding study in rats. The 2 mg/kg/day is the most conservative NOAEL taking into account that the endpoint is mortality and the steepness of the dose response curve.
	UF[1] = 100	**Acute RfD = 0.02 mg/kg/day, Acute PAD[2] = 0.002 mg/kg/day**	
Chronic Dietary (Non-cancer)	0.1	(RfD Committee 9/97) Increased mortality, increased absolute and relative liver weight, and hematological alterations at 1.0 mg/kg/day (LOAEL).	Lowest NOAEL in the most sensitive species and also no long-term studies available in the database (10x UF applied for use of subchronic study)
	UF = 1000	**Chronic RfD = 0.0001 mg/kg/day; Chronic PAD = 0.00001 mg/kg/day**	
Chronic Dietary (Cancer)	Although zinc phosphide is registered for use on food crops, no chronic toxicity or carcinogenicity studies were required because chronic exposure to zinc phosphide or its byproducts were considered to be negligible. Thus data are not available to classified zinc phosphide in terms of carcinogenicity.		
Dermal Absorption	Dermal exposure is not expected since baits are not absorbable and Zn phosphide powder is too polar to be absorbed through the skin. Skin should be protected with proper Personal Protective Equipment (PPE), including chemical-resistant gloves as required by the Worker Protection Standard for chemicals in acute dermal tox category III.		
Inhalation	There is potential for inhalation exposure. Zinc phosphide is classified as tox category I for acute inhalation, which meets the Worker Protection Standard's requirement for a respirator.		

[1]UF = Uncertainty Factor

[2]PAD = Population Adjusted Dose (where PAD = Acute or Chronic RfD/FQPA factor).

Please Note: In a meeting of the FQPA Safety Factor Committee (4/19/99), the Committee determined that the FQPA Safety Factor (for enhanced sensitivity of infants and children as required by the Food Quality Protection Act of 1996) should be retained for this active ingredient and is applicable to all subpopulations.

3.3.2 Classification of Carcinogenic Potential

Since chronic exposure and risk associated with the use of zinc phosphide is negligible, no risk of cancer is expected from the use of zinc phosphide.

3.4 Endocrine Disruptor Effects

EPA is required under the FFDCA, as amended by FQPA, to develop a screening program to determine whether certain substances (including all pesticide active and other ingredients) "may have an effect in humans that is similar to an effect produced by a naturally occurring estrogen, or other such endocrine effects as the Administrator may designate." Following the recommendations of its Endocrine Disruptor Screening and Testing Advisory Committee (EDSTAC), EPA determined that there was scientific bases for including, as part of the program, the androgen and thyroid hormone systems, in addition to the estrogen hormone system. EPA also adopted EDSTAC's recommendation that the Program include evaluations of potential effects in wildlife. For pesticide chemicals, EPA will use FIFRA and, to the extent that effects in wildlife may help determine whether a substance may have an effect in humans, FFDCA authority to require the wildlife evaluations. As the science develops and resources allow, screening of additional hormone systems may be added to the Endocrine Disruptor Screening Program (EDSP).

Currently, there are no data available to suggest that zinc phosphide will adversely affect the immune or endocrine systems.

When the appropriate screening and/or testing protocols being considered under the Agency's EDSP have been developed, zinc phosphide may be subjected to additional screening and/or testing to better characterize effects related to endocrine disruption.

4.0 Exposure Assessment

4.1 Summary of Registered Uses and Proposed Uses

Registered Uses

Zinc phosphide is a rodenticide currently registered as a bait/solid (1 - 2% a.i), dust (10 - 63% a.i), granular (2 - 63% a.i), pellet/tablet (2% a.i), wettable powder (80% a.i as pre-mix for bait) for use in food and non-food use sites.

> *Nonfood*: Indoor and outdoor residential and agricultural areas (including in and around homes, on lawns, around bulbs, in and around outside buildings/barns, rights-of-ways/fencerows/hedgerows), indoor and outdoor commercial or institutional premises and equipment (including food handling establishments), golf courses, reforestation areas, alfalfa, barley, berries (dormant), oats, sugar maple, wheat, no-till corn, macadamia nut orchards, orchards/groves (post-harvest and dormant), timothy (hay). Zinc phosphide can also be used as a general, wide area, Public Health Use pesticide.
>
> *Food*: grapes, rangeland grasses, and sugarcane. Artichokes and sugar beets have regional registrations in California; currently there are no labels that include use on artichokes.

Proposed Uses

All the petitions are IR-4 petitions and are minor use ("E") petitions. The proposed uses are on alfalfa, barley, dry bean, sugar beet, timothy, potato, and wheat to kill rodents. Tolerances with regional registrations have been requested. The desired region is WA, OR, and ID for all crops except alfalfa. For alfalfa, the desired region is WA, OR, ID, and CA.

Zinc Phosphide Pellets (EPA Reg. No. 2393-521), for use on all the proposed crops, contain 2.0% zinc phosphide and 98.0% inert ingredients. Zinc Phosphide Wheat Bait [56228-3], for use on barley and wheat only, contains 1.82% zinc phosphide and 98.18% inert ingredients. Applications will be made post-emergence and broadcast. Ground equipment is specified. One application will be made to dry bean and potato; two applications can be made to alfalfa, barley, sugar beet, timothy, and wheat. Proposed PHIs are 30 days (alfalfa, dry bean, sugar beet, potato), 50 days (barley and wheat), or 158 days (timothy). The seasonal application rates are 0.12 lb ai/A/season for dry bean, 0.2 lb ai/A/season for potato, 0.24 lb ai/A/season for barley and wheat, and 0.4 lb ai/A/season for alfalfa, sugar beet, and timothy.

Table 4 lists the proposed use patterns for alfalfa, barley, bean (dry), beet (sugar), potato, timothy, and wheat. HED has determined that the proposed broadcast applications of zinc phosphide on these crops should be classified as food uses and that LOQ-level tolerances on human foods would be appropriate.

Table 4. Proposed Uses of Zinc Phosphide

Applic. Timing, Type, and Equip.	Formulation [EPA Reg. No.]	Applic. Rate (lb ai/A)	Max. No. Applic. per Season	Max. Seasonal Applic. Rate (lb ai/A)	PHI (days)	Use Directions and Limitations
Alfalfa						
post-emergence, broadcast, ground equipment	Zinc Phosphide Pellets [2393-521]	0.2	2	0.4	30	General*
Barley						
post-emergence, broadcast, ground equipment	Zinc Phosphide Pellets [2393-521]	0.12	2	0.24	50	All applications must be made prior to the boot stage. A minimum interval of 25 days between applications must be observed. General*
post-emergence, broadcast, ground equipment	Zinc Phosphide Wheat Bait [56228-3]	0.11	2	0.22	50	All applications must be made prior to the boot stage. A minimum interval of 25 days between applications must be observed. General**
Bean, Dry						
post-emergence, broadcast, ground equipment	Zinc Phosphide Pellets [2393-521]	0.12	1	0.12	30	General*
Beet, Sugar						
post-emergence, broadcast, ground equipment	Zinc Phosphide Pellets [2393-521]	0.2	2	0.4	30	General*
Potato						
post-emergence, broadcast, ground equipment	Zinc Phosphide Pellets [2393-521]	0.2	1	0.2	30	General*

Applic. Timing, Type, and Equip.	Formulation [EPA Reg. No.]	Applic. Rate (lb ai/A)	Max. No. Applic. per Season	Max. Seasonal Applic. Rate (lb ai/A)	PHI (days)	Use Directions and Limitations
Timothy						
Apply during crop dormancy. Broadcast, ground equipment.	Zinc Phosphide Pellets [2393-521]	0.2	2	0.4	158	A minimum of 158 days must pass between an application of zinc phosphide and any livestock foraging activity. General*
Wheat						
post-emergence, broadcast, ground equipment	Zinc Phosphide Pellets [2393-521]	0.12	2	0.24	50	All applications must be made prior to the boot stage. A minimum interval of 25 days between applications must be observed. General*
post-emergence, broadcast, ground equipment	Zinc Phosphide on Wheat [56228-3]	0.11	2	0.22	50	All applications must be made prior to the boot stage. A minimum interval of 25 days between applications must be observed. General**

* General use directions/restrictions for Zinc Phosphide Pellets [2393-521]:
Restricted use pesticide. Keep away from humans, domestic animals, and pets. This product is toxic to wildlife and fish. Birds and other wildlife feeding on treated pellets may be killed. Do not apply to open ground, roads and areas in which no vegetation occurs. Keep out of lakes, streams, ponds and all aquatic systems. Do not apply where runoff from this product will enter an aquatic system. Pellets must not be applied on roads, near residential areas, or over water. **Do not broadcast over growing crops other than sugarcane**. Apply pellets on warm, clear days. **Do not graze animals in treated areas.**

** General use directions/restrictions for Zinc Phosphide on Wheat [56228-3]:
Restricted use pesticide. Keep away from humans, domestic animals, and pets. This product is toxic to wildlife and fish. Birds and other wildlife feeding in treated areas may be killed. Keep out of lakes, ponds, or streams. This product shall not be applied over bodies of water, in areas inhabited by livestock, or where a hazard exists to rare or endangered species.

Label Deficiencies

A revised Section B/label is needed for alfalfa to specify that the pesticide is to be applied to freshly cut alfalfa fields after the removal of hay and before there is two inches of regrowth. (This restriction will lessen the risk that the pesticide will become lodged in the alfalfa plant from broadcast application.) Also, the Section B/label must be revised to indicate that alfalfa forage must not be harvested until it reaches maturity; and 2) For the Zinc Phosphide Pellet formulation, the statement "Do not broadcast over growing crops other than sugarcane" must be revised to include the proposed crops.

4.2 Dietary Exposure/Risk Pathway

4.2.1 Residue Profile

Background

Tolerances have been proposed for residues of phosphine resulting from the use of the rodenticide zinc phosphide (as specified under "zinc phosphide" in 40 CFR §180.284). The residue of concern for risk assessment is the unreacted zinc phosphide, measured as phosphine and quantitated as zinc phosphide using a GC calibration curve. IR-4 has proposed the establishment of the following permanent tolerances for residues of zinc phosphide:

Commodity	Proposed Tolerance (ppm)
alfalfa forage	0.1
alfalfa hay	0.1
barley grain	0.05
barley hay	0.05
barley straw	0.2
bean (dry)*	0.05
sugar beet (tops)	0.2
sugar beet (roots)	0.05
grass (timothy hay)	0.05
grass (timothy forage)	0.05
potato	0.05
Wheat grain	0.05
Wheat hay	0.05
Wheat straw	0.05

*New use, all other commodities have Section 18 tolerances established under 40 CFR §180.284(b).

Permanent tolerances are currently established [40 CFR §180.284(a)] for residues of phosphine resulting from the use of the rodenticide zinc phosphide in or on grape (0.01 ppm), grass

(rangeland) (0.1 ppm), and sugarcane (0.01 ppm). Tolerances with regional registration are established [40 CFR §180.284(c)] for residues of phosphine resulting from the use of the rodenticide zinc phosphide in or on globe artichokes (0.01 ppm), sugar beet (roots) (0.04 ppm), and sugar beet (tops) (0.02 ppm). Section 18 tolerances [40 CFR §180.284(b)] currently exist for residues of phosphine resulting from the use of the rodenticide zinc phosphide in or on alfalfa forage, alfalfa hay, barley grain, barley hay, barley straw, sugar beets (tops), sugar beets (roots), timothy hay, timothy forage, potato, wheat grain, wheat hay, and wheat straw.

Nature of the Residue

Plants: The nature of the residue in plants is adequately understood. The residue of concern in plants for risk assessment purposes is the unreacted zinc phosphide, measured as phosphine. Tolerances are established (40 CFR §180.284) for "residues of phosphine resulting from the use of the rodenticide zinc phosphide". A zinc phosphide radiotracer study demonstrated that sugarcane will absorb and translocate ^{32}P, but not as phosphine *per se*. The ^{32}P was shown to be thermally stable and non-volatile, and was assumed to be translocated through plants as phosphate. Based on this radiotracer study, EPA determined that the residue of concern is the unreacted zinc phosphide, measured as phosphine.

Livestock: Livestock metabolism data are not required. Residues of zinc phosphide ingested by livestock would be immediately converted to phosphine and metabolized to naturally occurring phosphorus compounds. There is no expectation of secondary residues in meat, milk, poultry, and eggs as a result of the registered or proposed uses.

Residue Analytical Methods

Acceptable methods are available for enforcement and data collection purposes for plant commodities. The *Pesticide Analytical Manual (PAM), Vol. II* lists, under aluminum phosphide, a colorimetric method and a gas liquid chromatography with flame photometric detection (GLC/FPD) method as Methods A and B, respectively. Both methods determine the level of phosphine liberated when zinc phosphide is exposed to dilute acid solutions. It is noted that Method A remains a lettered method because of variable recoveries observed in an Agency method try-out. However, EPA has determined that the method is acceptable for enforcement. Data submitted in support of the established tolerances were collected by one of these two methods. Data submitted in support of the proposed tolerances were collected by the GLC/FPD method or a similar method.

Multiresidue Methods (MRM)

Because zinc phosphide is an inorganic compound, recovery of residues using FDA Multiresidue Protocols is not expected, and the requirement for such data is waived.

Storage Stability

The storage stability studies are valid to demonstrate the level of stability of zinc phosphide in

stored samples of alfalfa forage and hay; barley grain, hay and straw; sugar beet roots and tops; potatoes; timothy forage; and wheat grain, hay, and straw. Based on corrected recoveries, zinc phosphide was stable in wheat straw at <-5°C for 78 days, barley hay at <-5°C for 93 days, and sugar beet tops at <-5°C for 650 days; however, the data indicate that residues of zinc phosphide are generally not stable during frozen storage in various crops. For matrices with losses in storage of ≤30% (i.e., potato tubers at approximately -18°C for 128 days, wheat grain and hay at <-5°C for 52 and 78 days, respectively; barley grain at <-5°C for 52 days, and sugar beet roots at <-5°C for 575 days), the residue data can be corrected for loss during storage. For matrices with losses on storage of >30% (i.e., timothy forage at <-5°C for 455 days, barley straw at <-5°C for 84 days, and alfalfa forage and hay at generally <-18°C for 206 and 891 days, respectively), residue data for zinc phosphide will also be corrected for loss during storage. Since residues of zinc phosphide are not stable in some crops, the submitted storage stability data cannot be translated to all crops.

Storage stability data for dry bean (stored 96 days) and timothy hay (stored 380 days) were not submitted. These data must be submitted as a condition of registration.

Magnitude of Residues in Plants

Alfalfa: The submitted data on alfalfa are adequate to support a proposed 0.2 ppm tolerance for residues of zinc phosphide in/on alfalfa forage and hay. The three field trials on alfalfa in ID are scientifically acceptable. The number and location of the field trials for alfalfa in ID (along with two field trials in CA) are not adequate for a full registration based on NAFTA representative growing regions but are adequate for a regional registration in CA, WA, OR, and ID.

The residue data, from three field trials on alfalfa in U.S. Region 11 (ID), reflect the use of zinc phosphide at the maximum seasonal application rate of 0.4 lb ai/A with PHIs of 28-32 days. Residues of zinc phosphide, uncorrected for loss on storage, were <0.05 ppm in/on all treated samples of alfalfa forage and hay. Significant residues (>30%) were lost from alfalfa forage and hay during storage; however, residues will be corrected for loss on storage. All residues at PHIs of 28-129 days were less than the LOQ's.

The two field trials on alfalfa in CA are scientifically acceptable. The number and location of the field trials for alfalfa are not adequate (along with three field trials in ID) for a full registration based on NAFTA representative growing regions but are adequate for a regional registration in CA, WA, OR, and ID.

The residue data, from two field trials on alfalfa in U.S. Region 10 (CA), reflect the use of zinc phosphide at the maximum seasonal application rate of 0.4 lb ai/A with PHIs of 20-25 days for forage and 25-35 days (including 5-10 days of field drying) for hay. Residues of zinc phosphide, uncorrected for loss on storage, were <0.05 -0.60 ppm in/on treated samples of alfalfa forage and <0.1 ppm in/on hay. (Residues in the forage in one study were 0.12-0.60 ppm at a 24-day PHI. This one study was an early season study in which the crop was dormant part of the time and the forage was not mature. Residues in

forage in the three other studies were <0.05 ppm at PHIs of 20-25 days. Significant residues were lost from alfalfa forage and hay during storage; however, residues will be corrected for loss on storage. Residues of zinc phosphide in forage decreased with increasing PHIs.

Barley: The submitted data on barley are adequate to support a proposed 0.05 ppm tolerance for residues of zinc phosphide in/on barley grain and a 0.2 ppm tolerance on barley hay and straw. The three field trials on barley in ID are scientifically acceptable. The number and location of the field trials for barley are not adequate for a full registration based on NAFTA representative growing regions but are adequate for a regional registration in WA, OR, and ID.

The residue data, from three field trials on barley in U.S. Region 11 (ID), reflect the use of zinc phosphide at the maximum seasonal application rate of 0.22-0.24 lb ai/A with PHIs of 50-60 days. Residues of zinc phosphide, uncorrected for loss on storage, were <0.05 ppm in/on treated samples of barley grain, ≤ 0.11 ppm in/on barley hay, and <0.1 ppm in/on barley straw. Since no detectable residues (<0.01 ppm) as well as no quantifiable residues (<0.05 ppm) were found in barley grain, residues corrected for loss on storage can be expected to be <0.05 ppm. Residues in barley hay were stable during frozen storage so residues in barley hay do not need to be corrected for loss on storage. Significant residues (>30%) were lost from barley straw during storage; however, residues will be corrected for loss on storage. No data demonstrating residue decline were submitted.

Dry Beans: The submitted data on bean (dry) are adequate to support a proposed 0.05 ppm tolerance for residues of zinc phosphide in/on bean, dry. The three field trials on dry beans in ID are scientifically acceptable. The number and location of the field trials for dry beans are not adequate for a full registration based on NAFTA representative growing regions but are adequate for a regional registration in WA, OR, and ID.

The residue data, from three field trials on dry beans in U.S. Region 11 (ID), reflect one application of zinc phosphide at the rate of 0.12 lb ai/A with a PHI of 31 days, followed by 7 days of field drying before collection. Residues of zinc phosphide, not corrected for loss on storage, were <0.05 ppm in/on all treated samples of dry beans. A storage stability study is not available for dry beans. Residue decline data were not provided.

Sugar beet: The submitted data on sugar beets are adequate to support a proposed 0.2 ppm tolerance for residues of zinc phosphide in/on sugar beet (tops) and a proposed 0.05 ppm tolerance for residues of zinc phosphide in/on sugar beet (roots). The three field trials on sugar beets in ID are classified as scientifically acceptable. The number and location of the field trials for sugar beets are not adequate for a full registration based on NAFTA representative growing regions but are adequate for a regional registration in WA, OR, and ID.

The residue data, from three field trials on sugar beets in U.S. Region 11 (ID), indicate

that residues of zinc phosphide, not corrected for loss on storage, were <0.05 ppm in/on sugar beet roots and <0.05 - 0.16 ppm in/on sugar beet tops at the seasonal application rate of 0.4 lb ai/A with PHIs of 28-29 days. In one exaggerated rate study (8 lb ai/A/season), residues (not corrected for loss on storage) were <0.05 ppm in roots and 1.2-3.4 ppm in tops at a PHI of 29 days. Residues in sugar beet tops were stable during frozen storage so residues in sugar beet tops do not need to be corrected for loss on storage. Since detectable residues were less than 0.01 ppm in sugar beet roots, residues corrected for loss on storage can be expected to be <0.05 ppm. No residue decline study was submitted.

Potato: The submitted five field trials on potatoes in ID are adequate to support the proposed 0.05 ppm tolerance for residues of zinc phosphide in/on potatoes. The number and location of the field trials for potato are not adequate for a full registration based on NAFTA representative growing regions but are adequate for a regional registration in WA, OR, and ID.

The residue data, from five field trials on potatoes in U.S. Region 11 (ID), reflect the use of zinc phosphide at the maximum seasonal application rate of 0.2 lb ai/A with PHIs of 28-31 days. Residues of zinc phosphide, uncorrected for some loss of residues on storage, were <0.05 ppm in/on all treated potato samples. Since no detectable residues (<0.01 ppm) as well as no quantifiable residues (<0.05 ppm) were found in potato tubers at 1X and residues at 5X were <0.05 ppm, residues corrected for loss on storage can be expected to be <0.05 ppm at 1X. No data demonstrating residue decline were submitted.

Timothy: The three field trials on timothy in WA are adequate to support the proposed 0.5 ppm tolerance for residues of zinc phosphide in/on timothy (hay) and timothy (forage). The number and location of the field trials for timothy are not adequate for a full registration based on NAFTA representative growing regions but are adequate for a regional registration in WA, OR, and ID.

The residue data, from three field trials on timothy in U.S. Region 11 (WA), reflect the use of zinc phosphide at the maximum seasonal application rate of 0.6 lb ai/A with PHIs of 61 and 158 days for timothy forage and 117 days for timothy hay. Residues of zinc phosphide, not corrected for significant loss of residues from timothy forage during storage, show that maximum residues of zinc phosphide reflecting application at the seasonal application rate of 0.6 lb ai/A are <0.05 ppm (<LOQ) to 0.15 ppm in timothy forage at a preharvest interval (PHI) of 61 days, <0.05 ppm in timothy forage at a PHI of 158 days, and <0.05 ppm in timothy hay at a PHI of 117 days. Significant residues (>30%) were lost from timothy forage during storage; however, residues will be corrected for loss on storage. Storage stability data for timothy hay were not provided. No data demonstrating residue decline were submitted.

Wheat: The three field trials on wheat in ID are classified as are adequate to support a proposed 0.05 ppm tolerance for residues of zinc phosphide in/on wheat forage, wheat grain, wheat hay, and wheat straw. The number and location of the field trials for wheat

are not adequate for a full registration based on NAFTA representative growing regions but are adequate for a regional registration in WA, OR, and ID.

The residue data, from three field trials on wheat in U.S. Region 11 (ID), reflect the use of zinc phosphide at the maximum seasonal application rate of 0.22-0.24 lb ai/A with PHIs of 56-60 days. Residues of zinc phosphide, uncorrected for loss on storage, were <0.05 ppm in/on all treated samples of wheat grain, hay, and straw. Since no detectable residues (<0.01 ppm) as well as no quantifiable residues (<0.05 ppm) were found in wheat grain and hay, residues corrected for loss on storage can be expected to be <0.05 ppm. Residues in wheat straw were stable during frozen storage so residues in wheat straw do not need to be corrected for loss on storage. No data demonstrating residue decline were submitted.

The following table (Table 5) summarizes the residues from crop field trials for zinc phosphide:

Table 5. Summary of Residues from the Crop Field Trials with Zinc Phosphide

Crop Matrix	Applic. Rate (lb ai/A)	PHI (days)	Residues (ppm)				
			Mean	Std. Dev.	HAFT	Min.	Max.
ALFALFA (proposed use = 0.4 lb ai/A total application rate, 30-day PHI)							
alfalfa, forage (ID)	0.4	28-32	<0.05	NA[1]	<0.05	<0.05	<0.05
alfalfa, hay (ID)	0.4	28-32	<0.1	NA[1]	<0.1	<0.1	<0.1
alfalfa, forage (CA)	0.4	20-25	0.12	0.16	0.33	<0.05	0.60[2]
alfalfa, hay (CA)	0.4	25-35	<0.1	NA[1]	<0.1	<0.1	<0.1
BARLEY (proposed use = 0.24 lb ai/A total application rate, 50-day PHI)							
barley, grain	0.22-0.24	50-60	<0.05	NA[1]	<0.05	<0.05	<0.05
barley, hay	0.22-0.24	50-60	<0.1	NA[1]	<0.08	<0.05	0.11
barley, straw	0.22-0.24	50-60	<0.1	NA[1]	<0.1	<0.1	<0.1
BEAN, DRY (proposed use = 0.12 lb ai/A total application rate, 30-day PHI)							
bean, dry	0.12	31	<0.05	NA[1]	<0.05	<0.05	<0.05
BEET, SUGAR (proposed use = 0.4 lb ai/A total application rate, 30-day PHI)							
beet, sugar, roots	0.4	28-29	<0.05	NA[1]	<0.05	<0.05	<0.05
beet, sugar, tops	0.4	28-29	0.08	NA[1]	0.10	<0.05	0.16
POTATO (proposed use = 0.2 lb ai/A total application rate, 30-day PHI)							
potato	0.2	28-31	<0.05	NA[1]	<0.05	<0.05	<0.05
TIMOTHY (proposed use = 0.4 lb ai/A total application rate, 158-day PHI)							
timothy, forage	0.6	158	0.07	NA[1]	0.10	<0.05	0.15
timothy, hay	0.6	117	<0.05	NA[1]	<0.05	<0.05	<0.05
WHEAT (proposed use = 0.24 lb ai/A total application rate, 50-day PHI)							
wheat, grain	0.22-0.24	56-60	<0.05	NA[1]	<0.05	<0.05	<0.05
wheat, hay	0.22-0.24	56-60	<0.05	NA[1]	<0.05	<0.05	<0.05
wheat, straw	0.22-0.24	56-60	<0.05	NA[1]	<0.05	<0.05	<0.05
wheat, forage	0.22-0.24	56-60	<0.05	NA[1]	<0.05	<0.05	<0.05

[1] Not applicable since all or most residues were <LOQ's.

[2] Residues in the forage in one study were 0.12-0.60 ppm at a 24-day PHI. This one study was an early season study in which the crop was dormant part of the time and the forage was not mature. Residues for forage in the three other studies were <0.05 ppm.

Magnitude of Residues in Processed Commodities

Processing studies are either not required or waived for the proposed uses for the following reasons: 1) There are no processed commodities for alfalfa, dry bean, and timothy (OPPTS

860.1000, Table 1); 2) Because no residues were found in samples treated at 5X, a processing study is not needed for potatoes; 3) No processing study is needed for sugar beets. Because zinc phosphide is not water soluble and reacts to form phosphine gas, HED believes that the washing and processing of sugar beets and refining of sugar will remove any unreacted zinc phosphide so that there is no likelihood of zinc phosphide residues occurring in the processed commodities; and 4) No processing study is needed for barley and wheat. HED believes that the processing of barley and wheat will decrease or remove any unreacted zinc phosphide so that there is no likelihood of zinc phosphide residues concentrating in the processed commodities.

Magnitude of Residues in Meat, Milk, Poultry, and Eggs

The requirements for data on the magnitude of the residue in livestock are waived. There is no reasonable expectation of residues in meat, milk, poultry, or eggs [Category 3 of 40 CFR §180.6(a)]. Residues of zinc phosphide ingested by livestock would be immediately converted to phosphine and metabolized to naturally occurring phosphorus compounds.

Confined and Field Accumulation in Rotational Crops

The confined and field accumulation in rotational crop studies are not required for zinc phosphide because the physical properties of zinc phosphide preclude transfer of residues to rotated crops. The Zinc Phosphide Consortium requested a waiver of the requirement for rotational crop studies based on the physical properties of zinc phosphide. Zn_3P_2 is essentially insoluble in water, making it largely immobile. It is also unstable in water at a pH other than 7.0, generally resulting in phosphorus ions being released from water as the largely insoluble gas, phosphine (PH_3), which is not likely to photodegrade, unstable in soil, decomposing to zinc oxide ions and phosphate ions, and is generally unstable under natural weathering conditions, slowly decomposing when contacted by ambient or soil moisture. Also, the PH_3 liberated during field use will either be rapidly and strongly absorbed by soil or diluted in the atmosphere, subsequently being degraded to the common natural ions, phosphorus and hydrogen.

International Harmonization of Tolerances

There are no international harmonization issues associated with this action since there are no Codex, Canadian, or Mexican maximum residue limits (MRLs) or tolerances for zinc phosphide on any crop.

4.2.2 Dietary Exposure Analyses

The Agency has previously concluded that acute or chronic dietary exposure associated with the use of zinc phosphide is unlikely (Zinc Phosphide RED, EPA 738-R-98-006, July 1998). In this assessment of dietary exposure and risk from the proposed uses of zinc phosphide it was also concluded that acute or chronic dietary exposure is unlikely. Thus, acute dietary, chronic dietary, and cancer assessments were not conducted for zinc phosphide. Residue data from field trials conducted to support the proposed registrations [alfalfa, barley, bean (dry), beet (sugar), potato, timothy and wheat] uphold the previous conclusion that acute or chronic dietary exposure to zinc phosphide in food is unlikely. Samples were analyzed by a properly validated method in which any zinc phosphide present was converted to phosphine using sulfuric acid; the phosphine was determined using GC/NPD. Residues were below the LOQs (<0.05 or <0.1 ppm) in most of the crops; the exceptions are livestock feeds. No detectable residues (<0.01 ppm) as well as no quantifiable residues (<0.05 ppm) were found in barley grain, wheat grain, sugar beets and potatoes; residues on these crops corrected for loss on storage can be expected to be <0.05 ppm. Although there is uncertainty regarding the stability of residues on dry beans, there is low concern for the possibility that exposure might be underestimated. Thus, these residue data provide considerable evidence that finite residues of zinc phosphide are not present on human food items. Despite the potential for zinc phosphide residues in grasses, sugar beets, and sugar cane, the Agency has determined that acute or chronic dietary exposure associated with the use of zinc phosphide is unlikely. Each of these commodities are not direct human food items; rather, they either are used as animal feeds (grasses) or undergone food processing prior to human ingestion (sugar cane, sugar beets). Because residues of zinc phosphide ingested by livestock would be immediately converted to phosphine and metabolized to naturally occurring phosphorus compounds, residues of zinc phosphide in livestock feeds are not expected to result in residues of zinc phosphide in livestock commodities. Also, zinc phosphide will not concentrate during the processing of any commodity because the act of processing will not allow for unreacted zinc phosphide to remain in or on processed food items.

4.2.3 Water Exposure/Risk Analyses

No drinking water risk assessment was performed for zinc phosphide because no residues are expected in either ground or surface water

4.2.4 Environmental Fate Analyses

The environmental fate assessment has been based on the review of available literature and is not supported by guideline studies. The major route of degradation/dissipation of zinc phosphide is hydrolysis, which results in the formation of volatile phosphine and zinc ions. Zinc phosphide and its residues appear to be non-persistent under most environmental conditions and relatively immobile (zinc ions and dissolved phosphorus readily sorb onto soil) in laboratory and field data. When applied to dry soil environments, zinc phosphide may be moderately persistent (40% of applied remaining at 30 days post-treatment). The rates of hydrolysis and volatilization of phosphine appear to be pH and soil moisture dependent with the hydrolysis rate increasing as the pH increases or decreases from neutrality. There are limited data available on the metabolism

(microbial mediated processes) of zinc phosphide. It is believed that zinc phosphide hydrolyzes prior to biotic metabolism, however, a potential metabolism process has not been described. It has been noted that in the presence of oxygen, soil organisms appear to utilize the decomposition products when present at low concentrations. Zinc phosphide degrades rapidly to Zn^{2+} and PH_3, which sorb strongly to soil and are common nutrients in soil. Zinc phosphide and its degradation products appear to have a low potential for ground water or surface water contamination. As discussed above, EFED has concluded dietary exposure to zinc phosphide residues are not expected from either ground or surface water-fed drinking water.

4.4 Residential Exposure/Risk Pathway

Zinc phosphide is currently registered in pellet and bait form for use on residential non-food sites to control mammals (primarily rodents) in areas such as commercial establishments, public areas (parks) dumps, and homes. A detailed residential exposure assessment is contained in the RED for zinc phosphide (RED Zinc Phosphide, EPA 738-R-98-006, July 1998). The residential exposure assessment evaluated exposure from accidental ingestion of zinc phosphide. No other residential exposure assessment was required. It is stated in the RED that the Agency believes that "accidental ingestion" of zinc phosphide baits should not be included in the FQPA determination for tolerance setting.

4.4.1 Incidental Oral Exposure and Risk

Zinc phosphide is currently registered for use on residential non-food sites. A detailed residential exposure assessment is contained in the RED for zinc phosphide (RED Zinc Phosphide, EPA 738-R-98-006, July 1998).

Although having considered that accidental ingestion of zinc phosphide baits may occur with respect to a very small number of children, EPA has concluded that this potential exposure is not appropriate for inclusion in evaluating the safety of aggregate exposure of consumers and major identifiable subgroups of consumers to zinc phosphide. Unlike other residential uses (such as a turf use) that potentially may result in exposures to significant groups of children, the subgroup of children that may consume baits is relatively and would not qualify as a major identifiable subgroup of consumers.

No other residential exposure assessment was required. The RED stated that the Agency believes that "accidental ingestion" of zinc phosphide baits should not be included in the FQPA determination for tolerance setting.

4.5 Incident Report Summary

The American Association of Poison Control Centers reported a total of 106 exposures to zinc phosphide in 1996. Six of these cases were suicide attempts. Approximately 80% of exposures occurred in residences and 62% of all cases involved children younger than 6 years of age. Ingestion was reported as the route of exposure in 60.5% of these cases, inhalation 18.4%, dermal 14%, ocular 2.6% and unknown in the remaining 3.5%. Excluding the suicide attempts,

13% reported symptoms that were considered potentially related to their exposure when they first contacted the Poison Control Center.

The Agency also consulted four incident databases and searched available literature. The OPP Incident Data System reports incidents submitted to the Agency since 1992 from various sources, including: registrants, other federal and state health and environmental agencies and individual consumers. The California Environmental Protection Agency (formerly the California Department of Food and Agriculture) has collected uniform data on suspected pesticide poisonings since 1982. In California, physicians are required to report all occurrences of illness suspected to be related to pesticide exposure; the majority of these occurrences involve occupational workers. The National Pesticide Telecommunications Network (NPTN) is a toll-free information service supported by OPP that includes incident reporting.

The limited information on human incidents is difficult to interpret. Many cases have been documented by the WHO, all prior to 1967. The high dosage associated with all of these cases (ten were fatal, ten non-fatal) would seem to indicate suicide or suicide attempts. The animal incidents identified by the databases are predominantly due to misuse or accidental exposure, with many of the exposures resulting in the death of the exposed animal.

On the list of the highest 200 chemicals for which NPTN received calls from 1984-1991, zinc phosphide was reported to be involved in 16 human incidents and nine animal incidents. Zinc phosphide ranked 165th in a ranking of 200 chemicals by the number of calls received. Incident data from Poison Control Centers was collected for 1989 and compared to the number of containers in U.S. homes in 1990. Of 83 compounds examined, zinc phosphide ranked 21st for number of exposures per million containers in homes, which was not unexpected for a bait product. None of the top ten compounds were rodenticide baits. For the 12 zinc phosphide cases where the exact product name was provided and an outcome determined, 2 cases reported minor and 1 case reported moderate effects. There were no major life threatening cases. No childhood deaths have been reported due to zinc phosphide since 1983 when the Poison Centers began systematic data collection.

5.0 Aggregate Risk Assessment and Risk Characterization

Zinc phosphide has both food and non-occupational uses; therefore, the considerations for aggregate exposure are those from food, drinking water and residential (non-occupational) sources.

HED has concluded that there will be no human dietary exposure from the proposed or registered uses of zinc phosphide. Thus, exposure to zinc phosphide from food is not a component of the acute and chronic aggregate exposure assessment.

As discussed above, zinc phosphide is registered for residential (non-occupational) uses. A residential exposure assessment has been completed in conjunction with the Zinc Phosphide RED (RED Zinc Phosphide, EPA 738-R-98-006, July 1998). The residential exposure assessment evaluated exposure from accidental ingestion of zinc phosphide. No other residential

exposure assessment was required. It is further stated in the RED that the Agency believes that "accidental ingestion" of zinc phosphide baits should not be included in the FQPA determination for tolerance setting. Thus, exposure from residential uses is not a component of acute and chronic aggregate exposure.

Short- and intermediate-term aggregate exposure takes into account chronic dietary food and water (considered to be a background exposure levels) plus indoor and outdoor residential exposure. No short- or intermediate-term dermal, oral or inhalation toxicological endpoints were identified for zinc phosphide. Thus, no short- or intermediate-term risk assessments are required.

As discussed above, there is no drinking water, residential, nor dietary component to acute and chronic aggregate exposure to zinc phosphide residues. Thus, acute and chronic aggregate exposure assessments are not required. Based on these risk assessments, EPA concludes that there is a reasonable certainty that no harm will result to adults, infants and children from aggregate exposure to zinc phosphide residues. Therefore, the Agency will not be performing an aggregate risk assessment for zinc phosphide.

6.0 Cumulative Risk

The Food Quality Protection Act (1996) stipulates that when determining the safety of a pesticide chemical, EPA shall base its assessment of the risk posed by the chemical on, among other things, available information concerning the cumulative effects to human health that may result from dietary, residential, or other non-occupational exposure to other substances that have a common mechanism of toxicity. The reason for consideration of other substances is due to the possibility that low-level exposures to multiple chemical substances that cause a common toxic effect by a common mechanism could lead to the same adverse health effect as would a higher level of exposure to any of the other substances individually. A person exposed to a pesticide at a level that is considered safe may in fact experience harm if that person is also exposed to other substances that cause a common toxic effect by a mechanism common with that of the subject pesticide, even if the individual exposure levels to the other substances are also considered safe.

HED has recently developed a framework that it proposes to use for conducting cumulative risk assessments on substances that have a common mechanism of toxicity. This guidance was issued for public comment on January 16, 2002 (67 FR 2210-2214) and is available from the OPP Website at:

http://www.epa.gov/pesticides/trac/science/cumulative_guidance.pdf.

In the guidance, it is stated that a cumulative risk assessment of substances that cause a common toxic effect by a common mechanism will not be conducted until an aggregate exposure assessment of each substance has been completed. Before undertaking a cumulative risk assessment, HED will follow procedures for identifying chemicals that have a common mechanism of toxicity as set forth in the "Guidance for Identifying Pesticide Chemicals and Other Substances that Have a Common Mechanism of Toxicity" (64 FR 5795-5796, February 5, 1999).

In the case of zinc phosphide, EPA has not yet determined whether or how to include this chemical in a cumulative risk assessment.

7.0 Occupational Exposure and Risk

The minimum level of PPE for handlers is based on acute toxicity for the end-use products. The Registration Division (RD) is responsible for ensuring that PPE listed on the label is in compliance with the Worker Protection Standard (WPS). The EPA-approved labels for the products (EPA Reg Nos. 56228-3 and 2393-521) included in this request only require workers to wear rubber gloves. Based on the potential for dermal and inhalation exposure, the Agency RED chapter for zinc phosphide recommends that all labels for occupational-use products require occupational handlers to wear waterproof gloves, protective eyewear and a dust/mist respirator when handling products containing zinc phosphide, unless those formulations are contained in ready-to-use bait stations or packaging that would eliminate the need to handle bait material directly.

In accordance with the Agency RED chapter for zinc phosphide, HED has concerns for mixer/loader/applicator exposure to zinc phosphide. However, no appropriate dermal or inhalation endpoints were identified by the HIARC for risk assessment. Based upon the physical properties of the chemical, dermal absorption is expected to be low. Therefore, RAB3 did not calculate daily doses or risk estimates for mixer/loader/applicators.

A previous Section 18 application proposed a 4 hour restricted entry interval (REI). However, in accordance with the zinc phosphide HED RED chapter, there are currently no restricted entry intervals for any zinc phosphide products. HED recommends that the following be added to the label: "Do not enter until dusts have settled," and for workers who reenter treated areas to collect carcases and uneaten baits, a requirement of chemical resistant gloves is recommended.

8.0 Data Needs/Label Requirements

8.1 Product and Residue Chemistry Data Requirements

PP#2E06419 Alfalfa

- ❑ A revised Section B/label is needed for alfalfa to specify that the pesticide is to be applied to freshly cut alfalfa fields after the removal of hay and before there is two inches of regrowth. (This restriction will lessen the risk that the pesticide will become lodged in the alfalfa plant from broadcast application.). Also, the Section B/label must be revised to indicate that alfalfa forage must not be harvested until it reaches maturity.

- ❑ A revised Section F must be submitted to propose tolerances on alfalfa, forage and alfalfa, hay at 0.2 ppm.

PP#1E06306 Barley

- ❑ A revised Section F must be submitted to propose a tolerance on barley, hay at 0.2 ppm.

PP#1E06270 Bean, dry

- ❑ Storage stability data were not provided for dry beans. Storage stability data for dry beans stored for 96 days must be submitted as a condition of registration.

PP#0E06199 Timothy

- ❑ A revised Section F must be submitted to propose a tolerance on timothy, hay and timothy, forage at 0.5 ppm.

- ❑ Storage stability data for timothy hay were not provided. Storage stability data for timothy hay stored 380 days must be submitted as a condition of registration.

PP#1E06292 Wheat

- ❑ A revised Section F must be submitted to propose a tolerance on wheat, forage at 0.05 ppm.

PP#1E06337 Beet, sugar

❑ None

PP#9E05082 Potato

❑ None

General

❑ A revised Section B/label is needed for the Zinc Phosphide Pellet formulation. The statement "Do not broadcast over growing crops other than sugarcane" must be revised to include the proposed crops if the proposed broadcast uses are registered.

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Chemical:

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